By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 644823**

Issued To: **Southmedic Inc.**
50 Alliance Blvd
Barrie
Ontario
L4M 5K3
Canada

In respect of:

Design, development and manufacture of Open oxygen delivery device with carbon dioxide monitoring; Oxygen mask with carbon dioxide monitoring; tubing, connectors, Nasal cannula, Adult and pediatric face masks (aerosol and oxygen); Tracheostomy oxygen masks; Sterile and non-sterile surgical blades, sterile and non-sterile disposable and safety scalpels and non-sterile vaginal pessary for the treatment of stress incontinence.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2016-01-23** Date: **2018-01-11** Expiry Date: **2023-01-10**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario M1L 3K2 Canada	**ETO Sterilization**
Steris Isomedix Services 184 Crown Court Whitby Ontario L1N 7B1 Canada	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
23 January 2016	8432655	Transfer from another Notified Body.
12 July 2017	8764391	Change of EU Rep address.
Current	8886083	CE Renewal. Removal of Wound Closure System from scope expression. Removal of Pepin Manufacturing as manufacturing subcontractor.